

WE CLAIM:

1. An electrode array for diagnosing the presence of a disease state in a living organism, said electrode array comprising:
 - a) a flexible body;
 - b) a plurality of flexible arms extending from the body; and
 - c) a plurality of electrodes provided by the plurality of flexible arms, wherein the electrodes are arranged on the arms to obtain impedance measurements between respective electrodes.
2. An electrode array according to claim 1 wherein the plurality of flexible arms are spaced around the flexible body.
3. An electrode array according to claim 2 wherein each of the plurality of flexible arms is provided with an electrode pair.
4. An electrode array according to claim 3 wherein the flexible body is provided with a stiffening member adapted to flatten part of the tissue of the living organism being diagnosed.
5. An electrode array according to claim 4 wherein the stiffening member is in the form of a ring.
6. An electrode array according to claim 4 wherein the stiffening member includes adhesive for fixation to the skin.
7. An electrode array according to claim 1 wherein each electrode comprises an adhesive for fixation to the skin.

8. An electrode array according to claim 7 wherein the adhesive is hydrogel.
9. An electrode array according to claim 7 wherein the adhesive is a gel foam pad.
10. An electrode array according to claim 9 wherein the gel foam pad forms a well that is filled with hydrogel.
11. An electrode array according to claim 1 wherein the flexible body and the flexible arms are comprised of a polyester film.
12. An electrode array according to claim 1 further comprising means extending at least partially between the electrodes to at least partially electrically isolate the electrodes from each other.
13. An electrode array according to claim 12 wherein said means comprises a ground conductive path.
14. An electrode array according to claim 13 wherein each of the plurality of flexible arms is provided with an electrode pair and each electrode pair is comprised of a current electrode and a voltage electrode.
15. An electrode array according to claim 14 wherein the ground conductive path extends at least partially between the current electrode and voltage electrode.
16. An electrode array according to claim 15 wherein each electrode is connected to an associated terminal by a conductive path.

17. An electrode array according to claim 16 wherein the ground conductive path extends at least partially between the conductive paths of respective electrodes to at least partially electrically isolate the conductive paths from each other.

18. An electrode array according to claim 17 wherein the ground conductive path extends at least partially between the terminals of respective electrodes to at least partially electrically isolate the terminals from each other.

19. An electrode array for diagnosing the presence of a disease state in a living organism, said electrode array comprising:

- a) a flexible backing material;
- b) a plurality of electrodes spaced around the backing material;
- and
- c) means extending at least partially between the electrodes to at least partially electrically isolate the electrodes from each other.

20. An electrode array according to claim 19 wherein said means comprises a ground conductive path.

21. An electrode array according to claim 20 wherein the plurality of electrodes comprise electrode pairs spaced around the backing material, and each electrode pair comprising a current electrode and a voltage electrode.

22. An electrode array according to claim 21 wherein the ground conductive path extends at least partially between the current electrode and voltage electrode.
23. An electrode array according to claim 22 wherein each electrode is connected to an associated terminal by a conductive path.
24. An electrode array according to claim 23 wherein the ground conductive path extends at least partially between the conductive paths of respective electrodes to at least partially electrically isolate the conductive paths from each other.
25. An electrode array according to claim 24 wherein the ground conductive path extends at least partially between the terminals of respective electrodes to at least partially electrically isolate the terminals from each other.
26. A method of confirming whether an electrode array for use in diagnosing a part of a living organism has been properly connected to an electronic module, the electrode array comprising a conductive path and a connector to link the conductive path to the electronic module, the method comprising:
- a) attaching the conductive path to a terminal of the connector;
 - b) connecting the electrode array to the electronic module using the connector; and
 - c) testing whether the conductive path is properly connected to the terminal of the connector.
27. A method according to claim 26 wherein the conductive path comprises a ground loop.

28. A method according to claim 27 wherein the terminal can be selected from a plurality of terminals of the connector.

29. A method according to claim 28 wherein the part of the living organism to be diagnosed is a breast of a person, and the conductive path is attached to a connector representing either the right or left breast.

30. A template for positioning an electrode array on a part of a living organism to be diagnosed for the presence of a disease state, the template comprising:

- a) a body having a plurality of spaced parallel lines; and
- b) at least two alignment marks positioned on the plurality of spaced parallel lines.

31. A template according to claim 30 wherein the body is elongate in a direction perpendicular to the parallel lines.

32. A template according to claim 31 wherein the body has at least one line extending perpendicular to the parallel lines.

33. A template according to claim 32 further comprising at least two alignment marks positioned on the line extending perpendicular to the parallel lines.

34. A template according to claim 33 wherein the body presents an opening through which at least a portion of the part of the living organism to be diagnosed is visible.

35. A template according to claim 34 wherein the alignment marks are spaced around the opening.

36. A template according to claim 35 wherein the body is comprised of a flexible and transparent material.

37. A method of positioning an electrode array on a part of a living organism to be diagnosed for the presence of a disease state, the electrode array positioned using a template, the template comprising a body having a plurality of spaced parallel lines and at least two alignment marks positioned on the plurality of spaced parallel lines, and the electrode array having at least two alignment marks corresponding to the alignment marks presented by the template, the method comprising:

- a) marking the living organism on or near the part to be diagnosed with a line;
- b) placing the positioning template on the part to be diagnosed and aligning at least one of the spaced parallel lines to the line marked on the living organism;
- c) marking on the living organism the location of the alignment marks of the template; and
- d) positioning the electrode array on the part to be diagnosed by aligning its corresponding alignment marks to the markings on the living organism from the template.

38. A method according to claim 37 wherein the template body has at least one line extending perpendicular to the parallel lines and at least two alignment marks positioned on such line.

39. A method according to claim 38 wherein the template body presents an opening through which at least a portion of the part of the living organism to be diagnosed is visible.
40. A method according to claim 39 wherein the alignment marks are spaced around the opening.
41. A method according to claim 40 wherein the line marked on the living organism is a vertical axis of the living organism.
42. A connecting member for connecting an electrode array for diagnosing the presence of a disease state in a living organism to a connector that electrically links the electrode array to an electronic module, the connector member comprising:
- a) a retaining member to receive the electrode array and connector in electrical contact with respect to one another; and
 - b) a clamping member to clamp the electrode array and connector together and secure the electrical contact therebetween.
43. A connecting member according to claim 42 wherein said clamping member comprises a compressive member to apply a compressive force to the electrode array and connector.
44. A connecting member according to claim 43 wherein the retaining member comprises a base and a projection extending from the base over which a portion of the electrode array and connector fit.
45. A connecting member according to claim 44 wherein the clamping member further comprises a washer to be positioned over the

projection extending from the base of the retaining member to engage the electrode array and connector.

46. A connecting member according to claim 45 wherein the base of the retaining member comprises at least one ridge extending from the base to engage the electrode array and connector on an opposite side from the washer.

47. A connecting member according to claim 45 wherein the projection is a threaded tube and the compressive member is a fastening nut.

48. A connecting member according to claim 47 wherein the base of the retaining member comprises at least two concentric ridges extending from the base to engage the electrode array and connector on an opposite side from the washer.

49. A connecting member according to claim 48 wherein the base further comprises alignment pins to ensure that the electrode array and connector are in correct electrical contact with respect to one another.

50. A connecting member according to claim 48 wherein the washer is provided with at least one channel adapted to fit therewithin the respective concentric ridges extending from the base.

51. A connecting member according to claim 48 wherein the washer is provided with at least two channels with each channel adapted to fit therewithin at least one of the ridges extending from the base.

52. A connecting member according to claim 48 wherein the washer is provided with at least two concentric ridges spaced to fit the respective concentric ridges extending from the base therebetween.

53. A method of connecting an electrode array for diagnosing the presence of a disease state in a living organism to a connector that electrically links the electrode array to an electronic module, the method comprising:

- a) placing the electrode array and connector in electrical contact with respect to one another; and
- b) clamping the electrode array and connector together to secure the electrical contact therebetween.

54. A method according to claim 53 wherein placing of the electrode array and connector in electrical contact with respect to one another is aided by a retaining member comprising a base and a projection extending from the base over which a portion of the electrode array and connector fit.

55. A method according to claim 54 wherein a clamping member is used to clamp the electrical array and connector together, the clamping member comprising a washer positioned over the projection extending from the base of the retaining member and to engage the electrode array and connector, and a compressive member to apply compressive force to the washer.

56. A method according to claim 55 wherein the base of the retaining member comprises at least one ridge extending from the base to engage the electrode array and connector on an opposite side from the washer.

57. A method according to claim 56 wherein the projection is a threaded tube and the compressive member is a fastening nut.

58. A method according to claim 57 wherein the base further comprises alignment pins to ensure that the electrode array and connector are in correct electrical contact with respect to one another.

59. A method of minimizing the number of connections in a conductive path of an electrode array for diagnosing the presence of a disease state in a living organism and a connector that electrically links the electrode array to an electronic module, the method comprising:

- a) providing a plurality of spaced unlinked conducting surfaces on the electrode array;
- b) providing a plurality of spaced unlinked conducting surfaces on the connector, with two of the conducting surfaces selected to be connected to the conductive path; and
- c) placing the electrode array and connector in electrical contact with respect to one another by overlapping the spaced unlinked conductive surfaces of the electrode array with the spaced unlinked conductive surfaces of the connector to form a continuous conductive path between the two selected conducting surfaces.

60. A method according to claim 59 wherein the spaced unlinked conducting surfaces on the electrode array are spaced generally around an opening provided by the array, and the spaced unlinked conducting surfaces on the connector are spaced around a similar opening provided by the connector.

61. A method according to claim 60 wherein the two selected conducting surfaces of the connector are adjacent to one another.

62. A method according to claim 61 wherein a gap is provided in the spacing of the unlinked conducting surfaces of the electrode array so that when the electrode array and connector are placed in overlapping relation the gap is positioned with respect to the adjacent selected conducting surfaces of the connector so that the continuous conductive path does not extend directly therebetween.

63. A method according to claim 62 wherein an alignment means is provided to ensure that the electrode array and connector overlies to form a continuous conductive path between the two selected conducting surfaces.

64. A method according to claim 63 wherein the conductive path is a ground conductive path.

65. A method of confirming an operable electrical contact between a plurality of spaced unlinked conducting surfaces of an electrode array and a plurality of spaced unlinked conducting surfaces of a connector, the method comprising:

- a) placing the electrode array and connector in electrical contact with respect to one another by overlapping the spaced unlinked conductive surfaces of the electrode array with the spaced unlinked conductive surfaces of the connector to form a continuous conductive path between two selected conducting surfaces; and
- b) measuring a test signal over the conductive path between the two selected conducting surface to see if an operable electrical contact has been established.

66. A method according to claim 65 wherein the conductive path is a ground conductive path.

67. A method according to claim 66 wherein electrical resistance is measured and compared to a pre-established value for an operable electrical contact.

68. A method according to claim 67 wherein placing the electrode array and connector in electrical contact with respect to one another places respective terminals for electrodes of the electrode array into electrical contact with respective conductive surfaces of the connector and the test establishes whether proper electrical contact between the respective terminals and conductive surfaces has been established.

69. A method of forming an electrode array for diagnosing the presence of a disease state in a living organism from a plurality of electrode array elements, wherein each electrode array element comprises a body having at least one arm extending from the body with at least one electrode provided on the arm, the method comprising:

- a) overlying the plurality of electrode array elements at the respective bodies thereof to form a main body of the electrode array with the arms of the respective electrode array elements extending from the main body in spaced relation; and
- b) clamping the plurality of electrode array elements together.

70. A method according to claim 69 wherein alignment means is provided to ensure that the arms of the respective electrode array elements extend around the main body of the electrode array in spaced relation.

71. A method according to claim 70 wherein a retaining member is used in clamping the plurality of electrode array elements together, and the retaining member comprises a stiffening member adapted to flatten part of the tissue of the living organism being diagnosed.

72. A method according to claim 71 wherein the stiffening member is in the form of a ring.

73. Apparatus for obtaining and processing impedance measurements from an electrode array for diagnosing the presence of a disease state in a living organism, the apparatus comprising:

- a) means to connect the apparatus to the electrode array;
- b) means to control the connection means to produce a set of impedance measurements;
- c) computer means to operate the control means; and
- d) means connected to the computer means to display the impedance measurements and any analysis thereof.

74. Apparatus according to claim 73 wherein the connection means comprises a multiplexer.

75. Apparatus according to claim 74 further comprising at least one EEPROM chip containing a selection pattern for producing the set of impedance measurements.

76. Apparatus according to claim 75 further comprising a counter to sequence the multiplexer through the set of impedance measurements.

77. Apparatus according to claim 73 wherein the display means comprises a printer.

78. Apparatus according to claim 73 wherein the display means comprises a display screen.

79. Apparatus according to claim 78 wherein each impedance measurement is displayed as a grid element.

80. Apparatus according to claim 79 wherein means are provided to identify the corresponding electrodes of the electrode array used to obtain the impedance measurement represented by a given grid element.

81. Apparatus according to claim 80 wherein the identifying means can be used to provide a value of the impedance measurement represented by the grid element.

82. Apparatus according to claim 81 wherein means can be provided on the display to indicate that the value of the impedance measurement represented by the grid element does not correspond to a predetermined expected value.

83. A method of testing a multiplexer using two substantially identical multiplexers, wherein one of the multiplexers will be reversely operated, the method comprising:

- a) connecting the respective outputs of the two multiplexers to one another;
- b) providing a calibration load to the input of the reversely operating multiplexer;
- c) simultaneously controlling operation of the two multiplexers through a sequence of identical output selections; and

d) measuring the calibration load at the input of the normally operating multiplexer.

84. A method according to claim 83 wherein the measurement of the calibration load is an impedance measurement.

85. A method of diagnosing the possibility of a disease state in one of first and second substantially similar parts of a living organism, the method comprising:

- a) obtaining a plurality of impedance measurements across predetermined portions of each of the parts to produce first and second sets of impedance measurements, the first set for the first part and the second set for the second part, and wherein each measurement of the first set has a corresponding measurement in the second set when taken across corresponding portions of each of the parts;
- b) identifying the set with a lower mean impedance value;
- c) creating an absolute difference set by subtracting each measurement of the set with the lower mean impedance value from the corresponding measurement of the other set; and
- d) analyzing the absolute difference set to diagnose the possibility of a disease state.

86. A method according to claim 85 wherein each of the first and second sets are arranged in respective mathematical matrices, and the absolute difference set is an absolute difference matrix.

87. A method according to claim 86 wherein the absolute difference matrix is used to calculate a matrix norm that is compared to a pre-established threshold to diagnose the possibility of a disease state.

88. A method according to claim 86 wherein the absolute difference matrix is used to calculate a matrix determinant that is compared to a pre-established threshold to diagnose the possibility of a disease state.

89. A method according to claim 86 wherein a sum of all of the values in the absolute difference matrix is calculated and compared to a pre-established threshold to diagnose the possibility of a disease state.

90. A method according to claim 86 wherein a visual display for diagnosing the location of a disease state is provided by summing the values in each of the absolute difference matrix columns and representing these sums in a bar graph.

91. A method according to claim 86 wherein a visual display for diagnosing the possibility of a disease state and its location is provided by plotting the value of each element in the absolute difference matrix as a function of the location of the element in the matrix.

92. A method of diagnosing the possibility of a disease state in one of first and second substantially similar parts of a living organism, the method comprising:

- a) obtaining a plurality of impedance measurements across predetermined portions of each of the parts to produce first and second sets of impedance measurements, the first set for the first part and the second set for the second part, and wherein each measurement of the first set has a corresponding measurement in the second set when taken across corresponding portions of each of the parts;

- b) creating a relative difference set by calculating the relative differences between each measurement from the first set with the corresponding measurement of the second set; and
- c) analyzing the relative difference set to diagnose the possibility of a disease state.

93. A method according to claim 92 wherein each of the first and second sets are arranged in respective mathematical matrices, and the relative difference set is an relative difference matrix.

94. A method according to claim 93 wherein the relative difference matrix is used to calculate a matrix norm that is compared to a pre-established threshold to diagnose the possibility of a disease state.

95. A method according to claim 93 wherein the relative difference matrix is used to calculate a matrix determinant that is compared to a pre-established threshold to diagnose the possibility of a disease state.

96. A method according to claim 93 wherein a sum of all of the values in the relative difference matrix is calculated and compared to a pre-established threshold to diagnose the possibility of a disease state.

97. A method according to claim 93 wherein a visual display for diagnosing the location of a disease state is provided by summing the values in each of the relative difference matrix columns and representing these sums in a bar graph.

98. A method according to claim 93 wherein a visual display for diagnosing the possibility of a disease state and its location is provided by

plotting the value of each element in the relative difference matrix as a function of the location of the element in the matrix.

99. A method of diagnosing the possibility of a disease state in one of first and second substantially similar parts of a living organism, the method comprising:

- a) obtaining a plurality of impedance measurements across predetermined portions of each of the parts to produce first and second sets of impedance measurements, the first set for the first part and the second set for the second part, and wherein each measurement of the first set has a corresponding measurement in the second set when taken across corresponding portions of each of the parts;
- b) calculating an impedance range by subtracting the minimum impedance measurement from either of the first and second sets from the maximum impedance measurement from such sets;
- c) creating a plurality of numbered bins by subdividing the impedance range into smaller range sizes then numbering the smaller range sizes consecutively;
- d) assigning a bin number to each of the impedance measurements from the first and second sets;
- e) creating a bin difference set by subtracting the bin number of each impedance measurement from one of the first and second sets from the bin number of each corresponding impedance measurement of the other set; and
- f) analyzing the bin difference set to diagnose the possibility of a disease state.

100. A method according to claim 99 wherein a sum of all of the bin difference values in the bin difference set is calculated and compared to a pre-established threshold to diagnose the possibility of a disease state.

101. A method of diagnosing the possibility of a disease state in one of first and second substantially similar parts of a living organism, the method comprising:

- a) obtaining a plurality of impedance measurements across predetermined portions of each of the parts to produce first and second sets of impedance measurements, the first set for the first part and the second set for the second part, and wherein each measurement of the first set has a corresponding measurement in the second set when taken across corresponding portions of each of the parts;
- b) calculating a first impedance range for the first set by subtracting the minimum impedance measurement from the maximum impedance measurement of that set, and calculating a second impedance range for the second set by subtracting the minimum impedance measurement from the maximum impedance measurement of that set;
- c) creating a plurality of first numbered bins by subdividing the first impedance range into a first set of smaller range sizes then numbering the first set of smaller range sizes consecutively, and creating a plurality of second numbered bins by subdividing the second impedance range into a second set of smaller range sizes then numbering the second set of smaller range sizes consecutively;
- d) assigning one of the first bin numbers to each of the impedance measurements from the first set, and assigning one

of the second bin numbers to each of the impedance measurements from the second set;

e) creating a bin difference set by subtracting the bin number of each impedance measurement from one of the first and second sets from the bin number of each corresponding impedance measurement of the other set; and

f) analyzing the bin difference set to diagnose the possibility of a disease state.

102. A method according to claim 101 wherein a sum of all of the bin difference values in the bin difference set is calculated and compared to a pre-established threshold to diagnose the possibility of a disease state.

103. A method of diagnosing the possibility of a disease state in one of first and second substantially similar parts of a living organism, the method comprising:

a) obtaining a plurality of impedance measurements taken between a predetermined plurality of points encircling the parts to produce first and second sets of impedance measurements, the first set for the first part and the second set for the second part, and wherein each measurement of the first set has a corresponding measurement in the second set when taken between a corresponding plurality of points;

b) assigning a bin number to each of the impedance measurements from the first and second sets;

c) producing a bin chord plot for each of the parts by graphically depicting the plurality of points as nodes as an encircling path for each part and the impedance measurements taken between the plurality of points as a bin chord extending between the respective nodes;

- d) dividing each graphical depiction into sectors; and
- e) analyzing the bin chords that converge on a given node within a sector to diagnose the possibility of a disease state.

104. A method according to claim 103 wherein each sector graphically displays the total number of bin chords that converge on all the nodes included within that sector.

105. A method according to claim 103 wherein the difference between corresponding bin chords for each part is plotted as a bin difference chord on the graphical depiction for the part having a lower bin number.

106. A method according to claim 105 wherein the calculation of the number of bin difference chords that converge on a given node is weighted depending on the differences between bin numbers from the first set and corresponding bin numbers from the second set.

107. A method according to claim 106 wherein each sector graphically displays the total number of bin difference chords that converge on all the nodes included within that sector.

108. A method according to claim 103 wherein the bin numbers are created by subdividing an impedance range obtained by subtracting the minimum impedance measurement from either of the first and second sets from the maximum impedance measurement from such sets into smaller range sizes then numbering the smaller range sizes consecutively.

109. A method according to claim 103 wherein the bin numbers are created by subdividing a first impedance range obtained by subtracting the

minimum impedance measurement from the maximum impedance measurement of the first set of impedance measurements into a first set of smaller range sizes then numbering the first set of smaller range sizes consecutively, and by subdividing a second impedance range obtained by subtracting the minimum impedance measurement from the maximum impedance measurement of the second set of impedance measurements into a second set of smaller range sizes then numbering the second set of smaller range sizes consecutively.

110. A method of diagnosing the possibility of a disease state in one of first and second substantially similar parts of a living organism, the method comprising:

- a) obtaining a plurality of impedance measurements taken between a predetermined plurality of points encircling the parts to produce first and second sets of impedance measurements, the first set for the first part and the second set for the second part, and wherein each measurement of the first set has a corresponding measurement in the second set when taken between a corresponding plurality of points;
- b) producing a pixel grid from a chord plot produced by the impedance measurements taken between the plurality of points; and
- c) analyzing the pixel grid to diagnose the possibility of a disease state.

111. A method according to claim 110 wherein the intensity of a pixel in the pixel grid is determined from the chords that pass through the pixel.

112. A method according to claim 111 wherein the number of chords, the impedance value of a chord, and the size of a chord segment that passes through the pixel are used in determining the intensity of the pixel.

113. A method according to claim 112 wherein the intensity of the pixels in the pixel grid is equalized to account for differences in the number of chords and the size of chord segments that pass through the various pixels to produce a pixel grid wherein pixel intensity indicates impedance value only.

114. A method according to claim 113 wherein the impedance intensity of the pixels is displayed visually.

115. A method according to claim 114 wherein the visual display of the impedance intensity of the pixels is generated by a computer to produce a plurality of levels to represent different levels of intensity.

116. A method according to claim 115 wherein the visual display generated by the computer has 256 levels to represent different levels of intensity.

117. A method according to claim 115 wherein the pixel grid is a pixel difference plot derived by subtracting corresponding impedance pixels from the plurality of points of the first part and the second part.

118. A method according to claim 115 wherein the pixel grid is a pixel difference plot derived by calculating the relative difference between corresponding impedance pixels from the plurality of points of the first part and the second part.

119. A method according to claims 117 or 118 wherein a constant, pre-established scale factor is applied to the impedance intensity of the pixels.

120. A method according to claims 117 or 118 wherein the pixel grid is divided into sectors and each sector graphically displays the sum of the impedance intensities for all pixels that are within the sector.

121. A method according to claim 113 wherein a pixel difference set is obtained by subtracting the pixel impedance value from one of the first and second sets from the pixel impedance value from each corresponding impedance measurement of the other set and the pixel difference set is analyzed to diagnose the possibility of a disease state.

122. A method according to claim 121 wherein a sum of all of the pixel difference values in the pixel difference set is calculated and compared to a pre-established threshold to diagnose the possibility of a disease state.

123. A method according to claim 121 wherein the pixel difference set is a pixel algebraic difference grid obtained by subtracting corresponding pixel impedance values taken between the plurality of points of the first part and the second part.

124. A method according to claim 121 wherein the pixel difference set is a pixel relative difference grid derived by calculating the relative difference between corresponding impedance values taken from the plurality of points of the first part and the second part.

125. A method according to claims 123 or 124 wherein the pixel grid is divided into sectors with each sector graphically displaying a sum of the impedance values for all pixels within that sector.